# Declaration of Conformity to MDR 2017/745 concerning Medical Devices

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| Manufacturer: | Beijing Choice Electronic Technology Co., Ltd.<br>2nd Floor, 3rd Floor and Room 410-412 4th Floor, No. 2 Building, No. 9 Shuangyuan Road, Shijingshan District, 100041 Beijing, PEOPLE'S REPUBLIC OF CHINA<br>SRN：CN-MF-000005776<br>Tel: +86-10-88203956 Fax: +86-10-88204632<br>E-mail: cc@choicemmed.com |
| European Representative: | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestrasse 80, 20537 Hamburg, Germany<br>Tel: +49-40-2513175 Fax: +49-40-255726<br>E-mail: shholding@hotmail.com |
| Product: | Pulse Oximeter |
| Model: | MD300CI216, MD300CI218, P300 Intelli IT(HPO-300T) |
| Basic UDI-DI: | 69428204SPO2VG |
| UMDNS Code: | 17148 |
| Classification: | Class IIa, rule 10 to Annex VIII of MDR 2017/745 |
| Conformity assessment Route: | Annex IX chapter I, chapter III, and section.4 |

**We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are sole responsible for the DoC.**

Standards applied:

EN ISO 13485:2016/A11:2021 Medical devices- Quality management systems- Requirements for regulatory purposes

EN ISO 14971:2019/A11:2021 Medical devices – Application of risk management to medical devices

IEC 60601-1: 2005+A1:2012+A2:2020 Medical electrical equipment-Part 1: General requirements for safety

EN 60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard：Electromagnetic disturbances - Requirements and tests

IEC 60601-1-11: 2015+A1:2020 Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

EN ISO 80601-2-61:2019 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

EN 60601-1-6:2010+A2-2021 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

EN 62304-2006+A1-2015 Medical device software-Software life-cycle processes

EN ISO 10993-1-2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN ISO 20417:2021 Medical devices - Information supplied by the manufacture

EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

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| Notified Body: | TÜV SÜD Product service GmbH<br>Ridlerstr 65, D-80339 München, Germany |
| Identification Number: | 0123 |
| (EC) Certificate(s) : | No. G10 057571 0008 Rev.00 |
| Start of CE-marking: | 2023-01-11 |
| Place, Date of Declaration: | Beijing, 2023-02-09 |
| Signature: | Haiying. Zhao<br>Name: Haiying Zhao<br>Position: Quality Director |